depositing a second binder liquid on the layer of powder immediately adjacent to the first binder liquid, wherein the first binder liquid provides a migration control barrier on the side adjacent to the second binder liquid.

20. The method of claim 19, wherein the first binder includes an auxiliary filler substance dissolved in it.

21. The method of claim 20, further including, allowing the first binder to substantially dry prior to depositing the second binder liquid.

22. The method of claim 19, wherein the first binder liquid includes as a solute an auxiliary filler substance which in solid form is more hydrophobic than the powder.

23. The method of claim 19, wherein the first binder liquid is an ethanol-based liquid and the second binder liquid is an aqueous liquid.

24. The method of claim 19, wherein the powder includes a migration control powder.

## REMARKS

Claim 7 was rejected under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter. Claim 7 has been amended for purposes of clarity and not to overcome prior art. Applicants submit that claim 7 is now in proper format for allowance. Claim 1-7, 9-12 and 14-18 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO 98/36739 issued to Yoo et al. ("Yoo"). Claims 1-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoo.

The Examiner has rejected all of the pending claims over Yoo. Anticipation under 35 U.S.C. § 102 "requires that each and every element of the claimed invention be disclosed in the prior reference." *Akzo v. Int'l Trade Comm'n*, 1 U.S.P.Q.2d 1241 (Fed. Cir.

1986). Yoo does not disclose each and every element of the bulk powder or the materials set, namely, Yoo does not disclose a migration control substance for controlling the migration of binder fluid. Further in view of the discussion below and the clarification with respect to the term "binder," applicants respectfully submit that these claims are patentable over Yoo.

An analysis under § 103 requires that the Examiner explain why, after assessing the level of those skilled in the art, the skilled artisan would have found the claimed subject matter, as a whole, to have been obvious. To establish a *prima fascia* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references, and there must be a reasonable expectation of success. MPEP § 706.02(j). The suggestion or motivation to make the claimed combination and a reasonable expectation of success must both be found in the prior art. *Id.* The Examiner cannot rely on hindsight as the basis for combining two references. If the references do not expressly or impliedly suggest the combination, "the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Id.* (*citing Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Inter. 1985)).

There is no motivation in the references themselves to combine these references. The Examiner has indicated that Yoo does not specifically state a method of controlling binder migration. The Examiner, however, takes the position that this is a syntax differentiation and that the migration controlling substance is known in the pharmaceutical art by the name "binder," citing to a Cosmetic Dictionary. The Examiner concludes that the binder itself prevents binder migration. (See page 5 of Office Action dated September 24, 2002).

Applicants are at a loss to comprehend how the Examiner concludes that the binder that is migrating is the same binder that is itself preventing binder migration. The present invention is specifically directed toward a separate binder migration substance for purposes of preventing migration of the binder in situations where the binder is in fact migrating. If the binder were able to control its own migration, this problem would not have presented itself.

Applicants offer further clarification with respect to the term "binder." Binder in the pharmaceutical context refers to the chemical entity that imparts the binding. In the present invention, the term binder is used to refer to the liquid-containing medium that goes through the

printhead to cause binding in the powder. In the pharmaceutical context, binders are traditionally used in two ways. The first is dry binding by direct compression on a tabletting machine. The second is wet binding in a step called wet granulation that precedes compression. Applicant asserts that it is not taught or well known in the art to use PLLA and PLGA as acceptable tabletting binders.

The Examiner accordingly has not succeeded in bringing a *prima fascia* case of obviousness in this instance. Claims 1-24 therefore are patentable under 35 U.S.C. § 103(a) over Yoo.

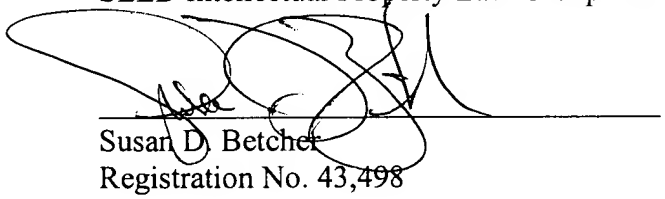
Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version With Markings to Show Changes Made.**"

Applicants respectfully submit that all claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Applicants' attorney wishes to express her willingness to engage in a telephone interview to further the status of this application if any further concerns need to be addressed.

Respectfully submitted,

Charles William Rowe et al.

SEED Intellectual Property Law Group PLLC



Susan D. Betcher
Registration No. 43,498

Enclosure:
Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 7 has been amended as follows:

1. A materials set for use in 3DP by deposition of a binder liquid onto a bed of powder, wherein the powder comprises:

a bulk powder substance; and

a migration control substance distributed within the bulk powder substance, the migration control substance soluble by the binder liquid wherein the migration control substance absorbs the binder liquid and forms a gel.

2. The materials set of claim 1, wherein the migration control substance swells when it absorbs the binder liquid.

3. The materials set of claim 1, wherein the bulk powder substance, the migration control substance and the binding liquid are all edible.

4. The materials set of claim 1, wherein the binder liquid includes water and the migration control substance is selected from the group consisting of cornstarch, starch, hydroxypropylmethyl celluloses, polyvinyl alcohols, polyoxyethylene oxides, polyethylene glycols, hydrophilic silica gel, xantham gum, gellan gum, locust bean gum, acrylic acid polymers, gelatin, sodium carboxymethyl cellulose, methylcellulose, guar gum, sodium alginate, and polyethylene-polypropylene copolymer.

5. The materials set of claim 1, wherein the binder liquid includes ethanol and the migration control substance is selected from the group consisting of polyethylene glycols, polyethylene-polypropylene copolymers, polyoxyethylene alkyl ethers, polyvinyl pyrrolidones, and hydroxypropylmethylcellulose.

6. The materials set of claim 1, wherein the bulk powder substance is selected from the group consisting of lactose, other sugars, microcrystalline cellulose, hydroxypropylmethylcellulose, methacrylic ester copolymers, or a pharmaceutical excipient.

7. (Amended) The materials set of claim 1, wherein the particles of the bulk powder substance comprise at least approximately 60% by weight of the powder and 40% by weight of the migration control substance.

8. The materials set of claim 1, wherein the particles of the migration control substance have an average particle size of less than approximately 38 microns.

9. The materials set of claim 1, wherein either the binder liquid or the bulk powder substance or the migration control substance comprises an active pharmaceutical ingredient.

10. The materials set of claim 1, wherein the binder liquid further comprises suspended solid particles.

11. A materials set for use in 3DP by deposition of a binder liquid onto a bed of powder, comprising:

liquid binder including a binding substance dissolved therein;

a bulk powder substance; and

a migration control substance intermixed with the bulk powder substance, the migration control substance dissolves in the binder liquid making a resulting solution which is more viscous than the binder liquid.

12. The materials set of claim 11, wherein the binder liquid includes water and the migration control substance is polyvinyl pyrrolidone.

13. The materials set of claim 11, wherein the binder liquid includes ethanol and the migration control substance is methacrylate or methacrylic ester copolymer.

14. The materials set of claim 11, wherein the migration control substance and the binding substance are the same substance.

15. The materials set of claim 11, wherein either the binder liquid or the bulk powder substance or the migration control substance includes an active pharmaceutical ingredient.

16. The materials set of claim 11, wherein the binder liquid further includes suspended solid particles.

17. A method of manufacturing a dosage form by 3DP, comprising:

depositing a layer of powder, wherein the powder includes particles of a bulk powder substance and particles of a migration control substance;

depositing onto the powder in selected places a binder liquid, wherein the binder liquid comprises a binding substance dissolved in it and wherein the migration control substance absorbs the binder liquid, thereby inhibiting migration of the binder liquid; and

repeating the above steps as many times as needed to manufacture the dosage forms.

18. A method of manufacturing a part by 3DP, comprising the steps of:

depositing a layer of powder wherein the powder includes particles of a bulk powder substance and particles of a migration control substance;

depositing onto the powder in selected places a binder liquid, wherein the migration control substance dissolves in the binder liquid making a resulting solution which is more viscous than the binder liquid; and

repeating the above steps as many times as needed to manufacture the part.

19. A method of controlling binder migration in three-dimensional printing, comprising:

depositing a layer of powder;

depositing a first binder liquid on the layer of powder; and

depositing a second binder liquid on the layer of powder immediately adjacent to the first binder liquid, wherein the first binder liquid provides a migration control barrier on the side adjacent to the second binder liquid.

20. The method of claim 19, wherein the first binder includes an auxiliary filler substance dissolved in it.

21. The method of claim 20, further including, allowing the first binder to substantially dry prior to depositing the second binder liquid.

22. The method of claim 19, wherein the first binder liquid includes as a solute an auxiliary filler substance which in solid form is more hydrophobic than the powder.

23. The method of claim 19, wherein the first binder liquid is an ethanol-based liquid and the second binder liquid is an aqueous liquid.

24. The method of claim 19, wherein the powder includes a migration control powder.

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